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EXAMINER
SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/582,817	REMACLE, JOSE	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-34,40,41,43-45,47,49 and 51-63* is/are pending in the application.

4a) Of the above claim(s) *32,33,49 and 51-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30,31,34,40,41,43-45 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 40 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the present case, claim 40 depends from canceled claim 39.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 30, 31, 34, 40, 41, 43-45, and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude

that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

5. For convenience, claim 30, the sole independent claim under consideration, is reproduced below.

30. **(Currently amended)** A method for the detection of a target molecule present in a sample, comprising the steps of:

allowing binding between said target molecule and a capture molecule fixed upon a side of the surface of a solid support, said solid support comprising a compact disc (CD) or DVD comprising registered data that can be read by a CD reading device, wherein said binding occurs in areas separated from areas comprising registered data ~~results in a detectable signal, and wherein said disc comprises registered data located on areas separated from the areas where the signal is generated~~;

treating said CD or DVD in order to obtain a detectable signal resulting from the binding of the target molecule and said capture molecule, wherein said binding results in a precipitate on said CD or DVD;

detecting said signal, wherein said signal is not obtained through cleavage of the capture molecule, and

reading the registered ~~information~~ data and reading the signal resulting from the binding between said target molecule and said capture molecule, said readings being done in an apparatus comprising by two different reading devices.

6. For purposes of examination, the term "target molecule" has been interpreted as encompassing virtually any and every molecule that can be detected directly, or indirectly, and further comprises any and all molecules associated with biological systems as well as non-biological systems. Support for this broad interpretation of the terms is based in part on the exemplary and non-limiting definition as found at page 14 and 15 of the disclosure, which for convenience, is reproduced below.

"Target" molecules and "capture" molecules

"Target" and "capture" molecules can be any kind of biological and chemical compounds, which are able to create a binding (or a specific fixation) between each other, said binding or the result of said binding can be detected by a reading device, preferably by using a light beam, preferably a laser beam.

***

Preferably, said "target" and non-cleavable "capture" molecules are synthetic or natural molecules selected from the group consisting of nucleic acids, antibodies, saccharides, lipids, peptides, proteins, lectins, catalysts, receptors, agonists or antagonists of receptors, fluorophores, chromophores, chelates, haptens, ions, molecules having different chiral structures, new synthetic chemical macro-molecules obtained by combinatorial chemistry or other functionalized macrostructures, portions or a combination thereof.

7. Said claims have also been interpreted as encompassing performance of any part of the assay, including fluid flow, binding, manipulation of reagents, etc., while at the same time having the disc rotate at any speed such that information stored in groves (e.g., the binary information of claim 45) is read and any signal so produced in the course of the assay is also detected and interpreted (claim 43).

8. Said claims have also been interpreted as encompassing a disc where reagents, binding areas and detection areas are located within groves.

9. A review of the specification finds that only certain types or sizes of discs are adequately described. Page 7 states that the discs are 1.2 mm thick and 12 cm in diameter. Also, page 12 of the disclosure provides added description of the disc to be used in the claimed method. As seen therein, the disc can range from 5 cm to 30 cm and varies in thickness from l mm to 2 mm. The specification has not been found to provide an adequate written description of alternative sizes/dimensions for discs to be used in the claimed method. Accordingly, applicant is urged to consider narrowing the claims to those embodiments adequately described.

10. As noted above, the claimed method has been interpreted as encompassing use of a disc where the reagents, binding, and detection all take place in grooved areas, as well as the recording and reading/interpretation of registration (binary) data. Page 18 of the disclosure, however, cautions the skilled artisan not to place capture moieties in grooved areas so as to avoid false positive signals. Page 25, second paragraph, discloses the binary information being located in pits, preferably in the grove adjacent to the non-cleavable capture molecule." Such teachings do not reasonably suggest that applicant has possession of a method whereby capture moieties and the assay in general is conducted in grooves located on or in a disc of any dimension.

11. A review of the disclosure finds that several documents have been cited, and in some instances the specification indicates that one may wish to "see" a given document. The aspect of encouraging one to "see" a document is not considered to constitute an incorporation-by-reference. Accordingly, the documents cited are not considered to constitute a part of the disclosure other than background.

12. The specification has been found to provide the following examples:

- Example 1, pages 26-28, "Detection of DNA on CD." The disc does not comprise registered data, and the binding of DNA to a probe is not achieved by using any "apparatus comprising two different reading devices." Rather, a picture of the CD was taken.
- Example 2, page 28, "Detection of DNA on CD with maser [laser; *sic*] detection." Following the application of a silver stain (precipitate), "[t]his CD was recovered with a gold layer to allow a laser CD player to read information written on the CD and to read the interference due to silver precipitate (Fig. 2 and 3)." The specification is silent as to the CD reader comprising "two different reading devices."
- Example 3, pages 28-30, "Detection of protein on CD by light absorption." The disc does not comprise registered data, and the formation of immunoglobulin – BSA-immunoglobulin-peroxidase was not detected with any "apparatus comprising two different reading devices." Furthermore, the method does not comprise any reading of any registration data. A picture of the CD was taken.
- Example 4, page 30,"Detection of proteins on CD with laser detection." Similar to Example 3, but the CD was read by a CD reader. Again, no registration data read, and the readings were not performed in an apparatus comprising two different reading devices.
- Example 5, pp. 30-31, "Magnetic detection of DNA or protein on CD." Prophetic statements of how hybridized DNA or protein on CD can be detected by a magnetic process. No method steps, starting materials, or reaction conditions described.

13. As seen above, none of the examples recite the method steps found in claim 30, the only independent claim under consideration. Clearly, none of the examples teach using a DVD.

14. In Example 2 it is noted that streptavidin-colloidal gold was used to detect biotinylated DNA spotted on the CD. Subsequent to the binding of streptavidin-colloidal gold to the biotinylated probe, "the CD was further incubated 30 min in a solution made of equal volume of Solution A and B from Silver enhancement kit (Sigma, St. Louis, USA) in order to have silver precipitate where positive hybridization occurred. This CD was recovered with a gold layer to allow a laser CD player to read information written on the CD and to read the interference due to silver precipitate (Fig. 2 and 3)." So while the specification does set forth means for reading information on a disc and for detecting signal (silver precipitate), such is of but a single embodiment and then requires additional steps. The specification does not set forth in sufficient detail the claimed method of detecting precipitates or the fixation of but one molecule (claims 30 and 40-41) to the capture molecules. Further, the specification does not set forth in sufficient detail any assay format where the reagents are allowed to bind to one another while the disc is spinning, wherein said spinning takes place at virtually any speed and wherein the reagents are on any exposed surface of the disc. While applicant has asserted that the claimed invention can be practiced in such a manner, a review of the disclosure fails to find an adequate written description of such a methodology such that it reasonably suggest that applicant was in possession of said method at the time of filing.

15. The specification is similarly silent as to how one is to read any registration (binary) data when the reading of such information is to occur subsequent to any binding and when the surface of the CD has been coated with an agent that would limit non-specific binding a the coating of

the entire surface of the CD would effectively block the reading of binary data recorded in other regions of the CD's track.

16. Claims 30, 34, 40, 41, 43, and 47 fairly encompass the detection of virtually any molecule. As shown above, the specification, at best, describes limited detection of hybridized nucleic acids and antigen-antibody binding. The specification does not provide any guidance as to how other molecules are to be detected. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

17. In accordance with claim 47, one is required to use the registered data in the "treatment" and "interpretation" of any signal. At no place does the specification provide an adequate written description as to how this is to be performed, much less provide an adequate written description of what data is to be recorded on the various discs and how it is in turn to be "used."

18. For the above reasons, and in the absence of convincing evidence to the contrary, claims 30, 31, 34, 40, 41, 43-45, and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Response to argument

19. While applicant has amended claim 30 so to recite treatment of the CD or DVD, and the manner in which the CD/DVD is to be read, the specification still does not provide an adequate written description of the claimed method so as to reasonably suggest that applicant had possession of the claimed invention at the time of filing. It is noted with particularity that the mere presence of verbiage so as to provide literal support for a limitation is not one and the same providing an adequate written description of the invention. Therefore, and in the absence of convincing evidence to the contrary, the rejection is maintained.

20. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

21. Claims 30, 31, 34, 40, 41, 43-45, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

22. Claim 1 recites the limitation " the detection " in line 1. There is insufficient antecedent basis for this limitation in the claim.

23. Claim 1 is indefinite as a result of the use of the abbreviation “DVD” without first defining the abbreviation.

24. Claim 40 is indefinite as it depends from a canceled claim 39.

25. Claim 41 recites the limitation "the fixation" in line 2. There is insufficient antecedent basis for this limitation in the claim.

26. Claim 47 recites the limitation "the treatment” and “the interpretation of the signal" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

28. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

29. Claims 30, 31, 34, 40, 41, 44, 45, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,030,581 (Virtanen) in view of US Patent 6,263,095B1 (Rushbrooke et al.).

30. Virtanen discloses a method of detecting nucleic acid wherein said nucleic acids are captured by a capture probe that is immobilized to a surface of a disc, wherein said disc is a CD, DVD.

31. Virtanen, column 5, discloses the analyte (applicant's elected species of nucleic acid) binding to predetermined locations on the disk. Said disc comprises at least two sections, one fox the assay and one where information is written and is separately read be a reader.

32. Virtanen does not disclose detection of the target molecule through signals such as fluorescence or precipitate.

33. Rushbrooke et al., teach at length of using imaging means to detect the presence of nucleic acids through detection of bound label that emits light; see column 4, penultimate paragraph. Column 8 explicitly addresses use of multiple labels in a single assay. Column 10 lists a variety of assay that can be conducted. Such assays include "high density arrays of oligonucleotides peptides, DNA proteins, carbohydrates or polysaccharides." Column 12 discloses use of fluorescent labels.

34. Column 11 provides advantages to the system.

35. The aspect of label moieties in solution binding to a target molecules located on a solid support is considered to meet the limitation of there being a precipitate upon the surface of the disc.

36. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the method of detection disclosed by Rushbrooke et a1., with that of Virtanen as the use fluorescent labels and detection of same via a CCD reader would provide for improved accuracy and ease of operation. In view of the detailed disclosure provided by Rushbrooke et al., said ordinary artisan would have had a most reasonably expectation of success.

Response to argument

Applicant, at page 6, bridging to page 7 of the response received17 May 2004, hereinafter the response, asserts that the rejection of claims under 35 USC 103(a) cannot be maintained.

Applicant, at page 7, states:

> Here, Virtanen teaches a disc platform for performing an integrated assay where all chemistry (mixing, washing, reacting, etc.) is performed inside the disk. Centrifugal force is the main force used to transfer liquids in the integrated bio-compact disk of Virtanen by using the rotation of the disk to spread fluids into the channels. Thus, the disk

> provided in the Virtanen reference is not a conventional CD or DVD but instead is a disk comprising multiple layers and elements such as microchannels or chambers which are in fluidic contact with one another. Further, in the Virtanen reference the assay is performed by mixing the components on a rotating disk while in the presently claimed methods the disk is not rotating when the binding step is performed. Furthermore, in Virtanen, the detection of the analyte is obtained through the cleavage of capture molecules. Therefore is indirect. In contrast, the present claims specify that detection is not obtained indirectly through cleavage of capture molecules but rather is directly obtained from a precipate [precipitate; *sic*].

The above argument has been fully considered and hs not been found persuasive towards the withdrawal of the rejection. It is noted with particularity that the claimed method does not proscribe using a CD or DVD disk that comprises reaction chambers and fluid channels. Additionally, the claimed method also does not require that the disk be static while permitting binding, washing, reacting, and detecting. In short, applicant is arguing limitations not present in the claims.

37. At page 7 of the response applicant presents argument that there is no motivation to incorporate the detection method of Rushbrooke et al., into the methodology of Virtanen.

38. The above argument has been fully considered and has not been found persuasive for as noted in the prior Office action, Rushbrooke et al., does provide motivation by teaching explicitly of benefits to be derived by using their detection system. As previously noted, and as can be seen at column 11, the direct detection of fluorescent signals emanating from a hybridized probe-target structure, one is able to achieve greater sensitivity.

39. While the claimed method states that a "precipitate" on the CD or DVD, it is noted that the detectable moiety in effect binds to the complementary nucleic acid strand, and in so doing forms a detectable precipitate. This embodiment if fairly encompassed by claim 34, which

stipulates that the one is to detect "the signal by …variation of an electromagnetic field." Fluorescence and luminescence are examples of just such an embodiment.

40. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

41. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

42. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

43. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
02 August 2004